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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,239	01/16/2002	Melissa M. Batchelor	RM.7CP	8033
29296	7590	04/01/2005	EXAMINER	
JULIA CHURCH DIERKER DIERKER & ASSOCIATES, P.C. 3331 W. BIG BEAVER RD. SUITE 109 TROY, MI 48084-2813			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,239

Applicant(s)

BATCHELOR ET AL

Examiner

David M. Naff

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-34 is/are pending in the application.
- 4a) Of the above claim(s) 20-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-19 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1651

DETAILED ACTION

An amendment of 1/3/05 submitted a substitute specification, amended claims 6, 7, 10, 13, 14, 18, 19, 30 and 31, canceled claims 1-5, and added new claims 32-34.

The substitute specification is accepted.

Claims 20-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/20/04.

Claims examined on the merits are 6-19 and 30-34.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-19 and 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Bridging lines 2 and 3 of claim 1 and in line 3 of claim 30, and where recited in other claims, "nitrite reductase-like activity" is uncertain as to meaning and scope. Being "like" nitrite reductase is relative and subjective, and it would be uncertain as to catalytic agents that are like and not like nitrite reductase.

In line 5 of claim 6 and bridging lines 2 and 3 of claim 30, and where recited in other claims, "biomimetic catalytic agent" is uncertain as to meaning and scope. The line of demarcation between biomimetic and non-biomimetic catalytic agents is uncertain.

Response to Arguments

Applicants urge that "nitrite reductase-like activity" is used to describe compounds that have the function of NiR enzymes, but do not fall within the strict definitional category of NiR enzymes. However, the claims do not have to be limited to this definition of "nitrite reductase-like activity". This term can be interpreted to include any compound that one may consider to have an activity "like" nitrite reductase, and being "like" is relative and subjective.

Applicants assert that "biomimetic catalytic agent" is defined in the specification at page 3, lines 17-19. However, this definition is only what is recited in the claims.

Art Unit: 1651

Applicants further urge that a general definition of "biomimetic" is imitating, copying or learning from nature or biological systems. Further that a biomimetic agent is a synthetic agent that performs the same function as an agent in a human body or physiological system. Whereas, a non-biomimetic catalytic agent may be catalytic, but does not mimic natural processes.

The argument is unpersuasive since being a synthetic agent that performs a body function will be relative and subjective. For example, the body can contain copper bound to protein or other material, which can be considered a metal-lignd complex as in dependent claims such as 7 and 8. A material that is a mimic or synthetic will depend on how much different from the corresponding natural material it must be to be a mimic or synthetic, and this can vary depending on individual interpretation of how much the difference there must be to be a mimic or synthetic.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1651

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Fauquex et al (5,990,289) or Staples et al (5,169,936) (both newly applied).

The claims are drawn to a material containing an immobilized catalytic agent having nitrite reductase, nitrate reductase or nitrosothiol reductase activity that converts nitrite, nitrate or nitrosothiols to nitric oxide when in contact with blood. The catalytic agent is a biomimetic catalytic agent such as a Cu(II) metal ion ligand complex.

Fauquex et al (col 2, lines 10-35) and Staples et al (col 7, lines 15-50) disclose Cu(II) bound to a polymeric material via a chelating group for use in purifying protein.

The Cu(II) bound to a polymeric material of Fauquex et al or Staples et al is a material as presently claimed. The Cu(II) is inherently capable of functioning as a nitrite reductase when in contact with blood to produce nitric oxide. The chelating group is a ligand as required by claims that require a ligand, and results in a Cu(II) metal ion ligand complex as in claim 8.

Claim Rejections - 35 USC § 103

Claims 15-18 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sivan et al (6,569,688) in view of

Art Unit: 1651

Fauquex et al or Stamples et al each taken with Fanning et al (5,858,792) (newly applied), and if necessary in further view of Tedeschi et al (6,645,518).

The claims require the material to be a metal or a medical device.

Sivan et al disclose an intravascular apparatus such as a stent, which can be made of a metal (col 3, lines 60-61), containing an immobilized enzyme such as a nitrogen oxide synthase to produce nitric oxide (col 3, lines 45-66 and col 4, lines 40-39).

Fauquex et al and Stamples et al are described above.

Fanning et al disclose using copper to reduce nitrate to nitrite (col 3, lines 15-20) and measuring nitrite from nitric oxide produced from nitrite (col 9, lines 1-10).

Tedeschl et al disclose a medical device such as a stent having a nitric oxide releasing coating (col 8, lines 30-49).

It would have been obvious to immobilize Cu(II) in place of the nitrogen oxide synthase of Sivan et al as suggested by Fauquex et al or Stamples et al immobilizing Cu(II) on a polymeric material since it would have been expected from Fanning et al that Cu can reduce nitrite to produce nitric oxide. If needed, Tedeschl et al would have further suggested a coating on a medical device that releases nitric oxide.

Art Unit: 1651

Conclusion

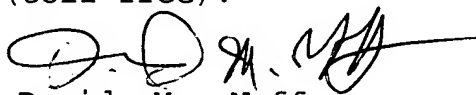
Claims 9, 13, 14, 19 and 34 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN

3/26/05